



Medtronic CryoCath LP

Technical Reference Manual

(For Hospital Biomedical Engineers)

TRM-002 MDT.2 CryoConsole Rev-00

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THIS MANUAL DOES NOT REPLACE THE OPERATOR'S MANUAL, ITS APPENDICES, AND THE INSTRUCTIONS FOR USE FOR EACH RESPECTIVE CATHETER.

THE TERM CATHETER IS USED THROUGHOUT THIS MANUAL TO DESCRIBE BOTH CARDIAC CRYOABLATION CATHETERS AS WELL AS SURGICAL CRYOABLATION DEVICES.

Section I General Information

I.1 Purpose

The purpose of this section is to give general information of the CryoConsole functionality, characteristic and accessories available.

I.2 Scope

This manual applies to the Medtronic CryoCath LP MDT.2 CryoAblation System Gen III (North American Ref#103A2, European Ref#103E2) as well as Gen IV system (North American Ref#104A2, European Ref#104E2). The CryoAblation Data Manager versions supported by this manual are 3.03 and 3.04.

I.3 Definitions and Acronyms

The following definitions and acronyms are used in this section:

MDT	Medtronic CryoCath LP
IEC	International Electro technical Commission
ISO	International Organization for Standardization
UL	Underwriters Laboratories
TLV	Threshold Limit Value
NIOSH	National Institute for Occupational Safety and Health
ECG	Electrocardiogram
CSA	Canadian Standards Association
MDD	Medical Device Directive
LRQ	Lois Refondues du Québec
7F/9F	7 French / 9 French
CE	Conformité Européenne
Sccm	Standard Cubic Centimeters per Minute
PSIa	Pound per Square Inch Absolute
KPa	Kilopascal

I.4 Warnings/Precautions

DO NOT ATTEMPT to service the MDT.2 CryoConsole.

Only technicians, fully trained by MDT, can service the CryoConsole.

Training courses and custom made tools are available at MDT.

Only the catheters, accessories, gas cylinders and spare parts that have been obtained from Medtronic CryoCath LP are to be used with the CryoConsole.

Even though the CryoConsole has passed the requirements of IEC 601-1 (UL report 75HN) it is the user's responsibility after installation and maintenance to verify and ensure that the CryoConsole meets the applicable electrical safety requirements.

Electrical Safety Test		
Test performed by:	Medtronic Field Engineer	Hospital BioMedical Engineer
	☐	☐

Print Name

Signature

Date (yyyy.mm.dd)

Nitrous Oxide Usage

- The MDT.2 CryoConsole operates on high-pressure liquid N₂O delivery. Store and handle the N₂O cylinder according to hospital gas management policy. Make sure to know their location for future needs.
- When using the CryoConsole during a procedure or during servicing, Nitrous oxide (N₂O) **must** be safely vented through the connected scavenging according to policies & procedures of each hospital in each country. Refer to the MDT.2 CryoConsole Operator's Manual for proper venting as described in Section IV – CryoConsole Pre-procedure set-up.
- Use only N₂O tanks supplied by Medtronic CryoCath LP.
- Use only Medtronic CryoCath LP supplied scavenging hose.
- Do NOT restrict or kink the scavenging hose.
- Do NOT disconnect the catheter or the scavenging hose from the MDT.2 CryoConsole until ALL N₂O is safely vented from the system (a few seconds after the end of the last injection).
- Cylinders are NOT for use on any other equipment.

- Threshold Limit Value (TLV) for N₂O is 25ppm as recommended by the National Institute for Occupational Safety and Health (NIOSH).
- Exposures to N₂O should be minimized to prevent short-term behavioural and long-term reproductive health effects.
- Do **not** open the N₂O gas tank valve until it is properly connected and tightened to the CryoConsole.
- Do **not** disconnect the high-pressure lines from the cylinder until the pressure gauges read '0' psi. Close the N₂O gas tank valve and allow the N₂O to safely vent from the system and lines, by turning the vent valve on the tank side counterclockwise, before disconnecting the high-pressure lines.

I.5 General Description

The Medtronic CryoCath LP CryoAblation System consists of three principal components:

- MDT.2 CryoConsole with CryoAblation Data Manager software
- The selected CryoAblation catheter
- Supplies and Accessories, including:
 - o Sterile/single use Coaxial Umbilical
 - o Sterile/single use Electrical Umbilical
 - o Non-sterile Auto Connection Box
 - o Non-sterile ECG Cable
 - o Gas Scavenging Hose
 - o Refrigerant Tank (N₂O cylinder)
 - o Power Cord
 - o Foot switch (Optional)



Figure 1 - The CryoConsole Gen III and Accessories



Figure 2 - The CryoConsole Gen IV and Accessories

Note: *Figure 1 and Figure 2 show the North American set-up (Nitrous Oxide tank)*

The European tank differs from the North American tank in size, weight and capacity. **Figure 3** shows the visual difference between the two.



Figure 3 - North American tank and European tank

The CryoConsole only operates in temperatures between 15°C and 30°C (60°F and 86°F), an altitude ranging from sea level to 2400 meters (8000 feet), and at a maximum humidity of 75%.

I.5.1. Description of the System

MDT.2 CryoConsole

The CryoConsole Gen III reference (103A2 and 103E2) is a type CF, 115/230v, 50/60Hz, 10amp, with respect to electric shock, fire, mechanical hazards in accordance with UL 2601-1: 1997 and CAN/CSA C22.2 No. 601.1, control number 75HN and IEC #601-1.

The CryoConsole Gen IV model (104A2 and 104E2) is a type CF, 115/230v, 50/60Hz, 10amp, with respect to electric shock, fire, mechanical hazards in accordance with CAN/CSA C22.2 No. 601.1-M90 file #220418 and IEC #601-1:1998.

Medtronic CryoCath LP recommends that the biomedical engineer of the site perform regular electrical leakage current measurements in order to ensure that the system leakage current does not exceed the allowable current as required by the applicable standards (IEC #601-1).

The CryoConsole houses the electrical, mechanical components and the software for controlling and recording the CryoTherapy procedure. It stores and controls delivery of liquid N₂O under high pressure through the coaxial umbilical to the catheter, recovers the refrigerant vapour from the catheter under vacuum, and disposes the refrigerant through the hospital scavenging system.

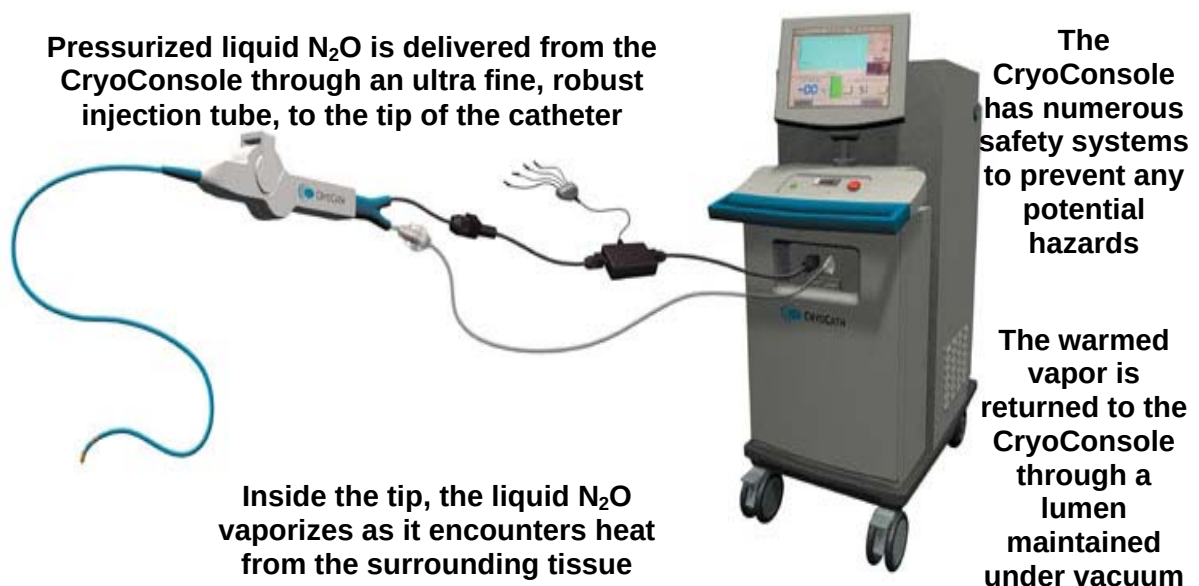


Figure 4 - The CryoConsole Gen III features

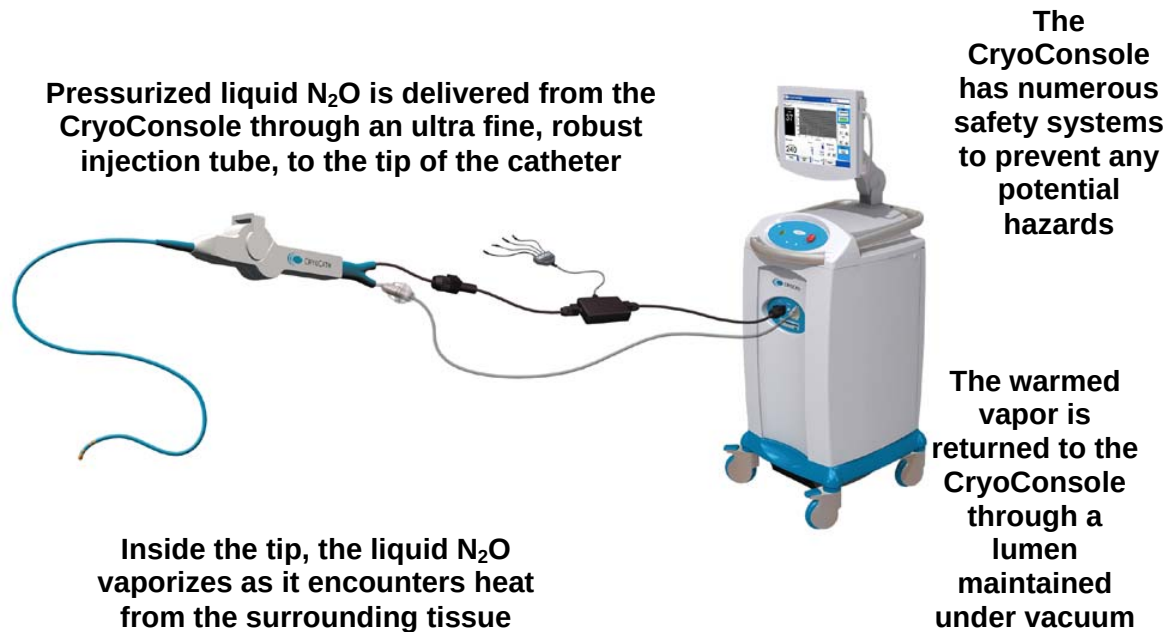


Figure 5 - The CryoConsole Gen IV features

The hardware controls the safety monitoring system while the software provides the interface to the patient information, procedure temperature, temperature set point, time set point and procedure data information.

Numerous safety systems exist to control the safe delivery of liquid N₂O to the catheter and the return of the vapour.

1. Inside the catheter

Vacuum System The shaft is always under vacuum unless blood is detected.

Leak Detection The leak detector detects blood ingress.

2. At the catheter handle

Blood Detection An infrared sensor inside the handle detects blood.

3. Inside the CryoConsole

Flow Detection The system monitors the flow of the returned N₂O vapour and will shut off the injection if the flow is outside the parameterized range.

Fluid Detection An ultrasound detector will disable the system if fluid is detected inside the console vacuum line.

Vent System The vent system sucks back the refrigerant.

When pushing the “Injection On” button for 2 second, the button lights up green, and the refrigerant injection begins. Injection stops when the red “Injection Off” button is pressed, when the timer runs out or when a system notice is triggered.

I.5.2. Accessories

The accessories include a sterile single use coaxial umbilical, a sterile single use electrical umbilical, an auto connection box and an ECG cable. During a medical intervention, the non-sterile accessories must be handled in such a way not to introduce them into the sterile field.

The electrical umbilical provides the electrical connection between the CryoConsole and the catheter through the auto connection box. The coaxial umbilical provides the refrigerant during injection and recovers the vapour from the catheter to the CryoConsole. The auto connection box and the ECG cable provide an interface between the catheter and a standard EP system.

The auto connection box has a mechanical relay that automatically connects the thermocouples upon injection and disconnects them when injection stops and the temperature at the distal end of the catheter reaches 32°C or above. The purpose of this feature is to reduce the noise superimposed on the intra-cardiac signal recording.

I.5.2.1. Optional Accessory

The foot switch serves as a remote control to start and stop the injection. The injection will start if the foot switch is pressed for more than 2.5 seconds. To stop the injection, the switch must be pressed for 0.5 second. The foot switch connector is located on the bottom back of the CryoConsole as shown in **Figure 6**. Using the foot switch does not change the functionality of the injection button. The reference number for the Gen III footswitch is 103FS and the reference number for the Gen IV footswitch is 104FS.



**Foot switch
connector**

Figure 6 - Foot switch connector

I.5.2.2. Connection Sequence

Connect the scavenging hose, the power cord and the optional foot switch (if applicable).

To connect the accessories in preparation for a case, first connect the non-sterile accessories to the CryoConsole:

- Auto connection box
- ECG Cable

Then introduce the sterile items into the sterile field and connect them from the sterile field:

- Sterile electrical umbilical
- Sterile coaxial cable
- CryoAblation catheter

Under no circumstances should any sterile coaxial or electrical umbilical be re-sterilized or re-used. All sterile products, once used, are to be discarded with accordance to hospital procedures.

Should the customer or Medtronic CryoCath LP Technologies request that any accessory be returned to Medtronic CryoCath LP for inspection, it must be disinfected, cleaned and packaged as per Medtronic CryoCath LP Quality guidelines. A Return Goods Authorization (RGA) number is necessary and is distributed by Medtronic CryoCath LP Customer Service. Non-sterile accessories should be cleaned with a dry cloth and stored with the CryoConsole after use.

Only accessories provided by Medtronic CryoCath LP can be used with the CryoConsole. Do not expose catheter or accessories to fluids or solvents.

I.6 Technical Specifications

MDT.2 CryoConsole (REF# 103A2, 103E2, 104A2, 104E2)

Regulatory Approvals: The MDT.2 CryoConsole Gen III reference (103A2 and 103E2) is a type CF, 115/230v, 50/60Hz, 10A, with respect to electric shock, fire, mechanical hazards in accordance with UL 2601-1:1994, CAN/CSA C22.2 No. 601.1, IEC 601-01, and control number 75 HN. The CryoConsole Gen IV reference (104A2 and 104E2) is a type CF (defibrillation proof), 110/120/230v, 50/60Hz, 10A, with respect to electric shock, fire, mechanical hazards in accordance with UL 2601-1:1997, EN/IEC 60601-1, CAN/CSA C22.2 No. 601.1-M90 CSA file #220418. MDD CLASS IIb - CE Mark Certificate of Conformity No: 0088/ LRQ 0959680 PMA approved device PO20045 MDL 32473 (Canada)

REF#	MDT.2 CryoConsole			
103E2 / 103A2 / 104E2 / 104A2	After power up, normal operating parameters are:			
	NA: 110V±10% 10 amps CE: 230V±10% 5 amps			
	At power up, the equipment could draw a transient current of 10% greater than the nominal values			
	Operational Parameters:			
	15°C to 30°C (60°F to 86°F) Maximum of 75% humidity Altitude from sea level to 2400 meters (8000 feet)			
	Dimensions:			
	Gen III		Gen IV	
	Metric	Imperial	Metric	Imperial
	H: 127 cm D: 82 cm W: 54 cm	H: 50" D: 32" W: 21"	H: 157 cm D: 58.5 cm W: 54.6 cm	H: 62" D: 23" W: 21.5"
	Weight:			
	Gen III		Gen IV	
	Metric	Imperial	Metric	Imperial
	145 kg (Without N ₂ O tank)	320 lbs (Without N ₂ O tank)	131 kg (Without N ₂ O tank)	289 lbs (Without N ₂ O tank)

Table 1 - CryoConsole Specifications

Accessories

The ECG cable and auto connection box provide an interface between the Medtronic CryoCath LP and a standard EP system (via 2mm touch proof connectors).

The scavenging hose is used to evacuate N₂O from the CryoConsole to the hospital gas-scavenging outlet.

The optional foot switch is a remote control to initiate and stop injection of refrigerant.

Copies of all the Regulatory Approvals are available upon request.

REF#	Accessories	Metric	Imperial
2037A	Auto connection box	L: 14 cm W: 7 cm H: 5 cm 0.5 kg (approx.)	L: 5.5" W: 2.5" H: 1.8" 1.1 lbs. (approx.)
2035W	ECG cable	L: 81 cm	L: 32"
103FS(GenIII) 104FS(GenIV)	Footswitch (optional)	L: 17 cm W: 15 cm H: 2.5 cm Cord Length: 6.7m	L: 6.5" W: 6.0" H: 1.0" Cord Length: 12'
1035C (1035CW) 1035D (1035DW) 1035E (1035EW) 1035F (1035FW)	Yellow Scavenging hose (White Scavenging hose)	L (1035C): 6.0 m L (1035D): 7.5 m L (1035E): 9.0m L (1035F): 10.5m ID: 0.75 cm OD: 1.375 cm	L (1035C): 20' L (1035D): 25' L (1035E): 30' L (1035F): 40' ID: 0.3" OD: 0.55"
1038N	Power cord North America	L: 2.5 m	L: 8' 2"
1038E	Power cord EU	L: 2.5 m	L: 8' 2"
1038U	Power cord UK	L: 2.5 m	L: 8' 2"
1038Y	Power cord Italy	L: 2.5 m	L: 8' 2"

Table 2 - Accessories Specifications

Refrigerant Tank

The refrigerant is liquid nitrous oxide (N₂O).

- European N₂O refrigerant tank – REF # 103NE
- North American N₂O refrigerant tank – REF # 103N2

The CryoConsole operates with a refrigerant tank that contains high-pressure liquid nitrous oxide (N₂O). Store and handle the nitrous oxide refrigerant tanks according to the hospital gas storage/management policy. Exposure to nitrous oxide should be minimized to prevent short-term behavioural and long-term reproductive health effects. Do not use Medtronic CryoCath LP refrigerant tanks on any other equipment. Use only the N₂O refrigerant tank obtained by Medtronic CryoCath LP. The Threshold Limit Value (TLV) for nitrous oxide is 25ppm as recommended by NIOSH, National Institute for Occupational Safety and Health.

N₂O Specifications

Description: Cryogenic liquid nitrous oxide.

Molecular Formula: N₂O (UN 1070) 99.5% liquid phase with humidity level less than 50ppm.

Gas Scavenging Requirements

The CryoConsole produces Nitrous Oxide (N₂O) waste gas that should be removed from the system. There are three options for scavenging. Selecting the appropriate scavenging method is the hospital's responsibility. Use only the scavenging hose obtained by Medtronic CryoCath LP.

Exhaust N₂O to Vacuum Scavenging System (Active Scavenging)

This is the Medtronic CryoCath LP recommended method for removing waste gas. The scavenging hose should be attached to a hospital evacuation or vacuum system. The hospital system should meet the following requirements:

Gas to be scavenged	Nitrous Oxide (N ₂ O)
Scavenging refrigerant flow	5000 sccm N ₂ O
Scavenging vacuum level	≥ 15 in Mercury (Hg), or ≥ 380mm Hg, or ≤ 7.4 psia, or ≤ 51 KPa
Scavenging hose length provided	approximately 6.1m/ 20' up to 18.3m/ 60'
Scavenging connector	DISS (Some adaptors for common connection systems are available)

Exhaust N₂O into a Non-recirculating General Ventilation System (Passive Scavenging)

If a non-recirculating general ventilation system is present in the hospital, the discharge end of the scavenging hose can be placed up in an exhaust vent and the N₂O will be vented out of the building. Care should be taken to ensure that the tubing is placed far enough into the duct system to prevent the N₂O from re-entering the room.

Exhaust N₂O Directly to Outdoors (Passive Scavenging)

Since the gas is under positive pressure, the discharge end of the scavenging hose can be exhausted directly outdoors. This can be accomplished by placing the end of the hose out a window or attached to a pipe placed through a wall or ceiling to the outdoors. Care must be taken to ensure that the discharge location is NOT an area where people are normally present or in close proximity to an outside air intake or window where the N₂O could re-enter the building. The standard scavenging hose length provided by Medtronic CryoCath LP is 10.5m/40' long. If a longer hose is required, please contact Medtronic CryoCath LP Customer Service.

Section II Functional System Description

II.1 Purpose

The purpose of this section is to give a basic knowledge of the functional system of the MDT.2 CryoAblation System, therefore ensuring that appropriate actions are taken.

II.2 Scope

This section briefly describes the functional system of the CryoConsole, introducing the software interface, the mechanical system, and the electrical system.

II.3 Definitions and Acronyms

The following definitions and acronyms are used in this section

MDT	Medtronic CryoCath LP
EP	Electrophysiology
LCD	Liquid Crystal Display
CDM	CryoAblation Data Manager
PID	Proportional-Integral-Derivative
CPU	Central Processing Unit
ISA BUS	Industry Standard Architecture BUS
AC	Alternating current
DC	Direct current
IDE	Integrated Drive Electronics

II.4 System Overview

The CryoConsole is a combination of mechanical assemblies controlled by electronic circuitry. Control interfaces are available on the front and back panels of the unit allowing the system to be integrated in EP Lab set-up.

The catheter electrical connection is fed to the system through an isolation interface located on the patient board. This electrical interface provides a protection against electrical hazards and protects the CryoConsole unit from defibrillator discharges.

The user interfaces with the CryoConsole through a LCD touch screen, two indicators and two controls located on the front panel of the CryoConsole. The LCD touch screen shows a series of menus for operation of the CryoConsole and display of relevant information. The user starts the application of a procedure by pushing the hardware injection “ON” button for 2 seconds and stops the procedure at any time by pressing the hardware injection “OFF” button.

When the optional foot switch is in use, the user starts the application of a procedure by depressing the footswitch for 2-3 seconds and stops the procedure at any time by depressing the footswitch for 0.5 seconds.

The watchdog system is the focal point of any data sent and received either to or from the software user interface. The watchdog system is the brain of the system control, which continually monitors the mechanical assembly state, user requests and process failure and/or warning detection. It also acts as an interface between the software/user and the mechanical plumbing, which ensures patient and user safety should the software fail.

II.5 Software Interface

II.5.1. Software Interface Overview

The CryoConsole includes the software called CryoAblation Data Manager (CDM) and the software called Boot Strap Module (v3.02 and above). The main role of the software is to acquire and display system data from the hardware, set procedure parameters, save procedure data on the system hard disk and offer some automatic operational features. At system start-up, the software initiates a system self test which ensures proper functionality of the watchdog system and other system and safety features. Should the self-test fail, the CDM disables the system in order to prevent the user from proceeding.

II.5.2. Boot Strap Module

The role of the Boot Strap Module is to detect and authenticate software upgrade MDT diskettes and then launch the upgrade. This application facilitates software upgrades without the need for a field service representative intervention. This software is installed on CryoConsole depending on the approved country of installation.

II.5.3. CryoAblation Data Manager (CDM)

From the main interface panel, the software provides four major functional areas for the user to access: the *CryoTherapy* Panel, the *Review Patient Records* Panel, the *Service System* Panel and the *Shut Down System* button.

Selecting the *Begin CryoTherapy* button brings up the Patient Data Panel where the patient information is entered and saved to the hard disk. Through this panel, the user initiates a CryoTherapy procedure.

When a CryoTherapy procedure is requested, the software ensures that a valid catheter is connected to the CryoConsole. When it is connected, the CDM downloads a catheter identification code stored on a smart chip located inside the catheter handle. The catheter code is used to identify a catheter specific file located on the hard disk of the CryoConsole. This file allows the software to program the user interface on the procedure panel and set their default values, and contains parameters required for the proper operation of the identified catheter.

During a procedure, the software continuously displays relevant information on the screen. The temperature profiles are saved to the hard disk for future recall. Data recording starts at the

beginning of an injection and stops when the temperature reaches +10°C after stopping the injection. This feature allows the recording of the temperature thawing profile.

If a warning or failure occur, the user is immediately notified. If a system failure is detected during the procedure, the software stops saving the temperature profiles and opens a separate file where it logs the current state of the system. This system state file contains the most recent 99 system failures.

Depending on the type of catheter connected, the CryoConsole controls the catheter in two different ways:

Temperature Control (only during CryoMapping):

During a procedure, pressurized refrigerant is delivered in order to reach and maintain a predetermined ablation temperature. This continuous temperature control assures a compensation for heat load changes due to the blood movement during cardiac cycles or due to changes in the contact between the catheter tip and the tissue.

Temperature control is performed using two control loops: a hardware pressure control loop and a software temperature control loop. The CDM controls the tip temperature by reading the current tip temperature and determines the required delivery pressure set point using a special algorithm based on digital proportional-integral-derivative (PID) compensator. The pressure set point is sent to the hardware pressure controller, which assures a continuous control of a proportional valve based on a pressure transducer reading.

Flow Control (for all catheters during CryoAblation):

During a CryoTherapy procedure, pressurized refrigerant is delivered to reach and maintain a specific pre-determined flow value. This flow value ensures optimal tip temperatures required for ablation. As in the temperature control case, two control loops are used: A hardware pressure control loop and the software flow control loop. The CDM controls the refrigerant flow by reading the flow meter and determining the required delivery pressure set point to maintain that flow using a special algorithm based on digital proportional-integral-derivative (PID) compensator.

Should the CDM fail, a redundant hardware system is implemented as part of the Watchdog system to monitor the pressure set point sent by the CDM. Furthermore, the Watchdog system monitors the state of the CPU and the software in order to detect a freeze or abnormal loops and takes action by placing the mechanical plumbing into a safe mode. Another important feature of the Watchdog system is to block the analog set point controlled by the CDM whenever an injection OFF is requested or a failure is generated.

If the *Review Patient Records* option is selected, a file manager panel is displayed. This allows the user to select from a list of previously run procedures. The selected file may then be opened for viewing, copied to a floppy disk, or deleted from the hard disk.

The third functional area, which can be selected from the main panel, is the Service System Panel. This is to aid certified service personnel in performing routine system maintenance and to help technical personnel in troubleshooting the system. To prohibit unauthorized personnel from accessing restricted system information, several troubleshooting panels are password protected.

The last functional area is the *Shut Down System* button. Before turning off the power of the CryoConsole, make sure to wait until the message “*It is now safe to turn off your computer*” is displayed on the screen.

II.5.4. Catheter Files

Each catheter used with the CryoConsole requires different settings of operations. Therefore, the data for each catheter is stored in a catheter file. When a catheter is approved for use with the CryoConsole, the associated catheter file is installed in the appropriate directory.

II.5.5. Hardware File

The CryoConsole uses a binary file called *Hardware file* which contain the necessary parameters for interpreting analog signals including the appropriate tank formula for the calculation of remaining N₂O. The hardware file is dependant of the CDM software version and the CDM software is configured to load the appropriate file based on the console configuration (North American, European, or other).

II.6 Mechanical System

II.6.1. Mechanical System Overview

The mechanical assembly delivers a controlled pressurized refrigerant to the catheter, recovers the refrigerant vapour from the catheter and evacuates the residual refrigerant from the catheter at the end of the injection. The mechanical system can be split into the following three sub-systems:

- Refrigerant delivery plumbing
- Refrigerant recovery system
- Refrigerant evacuation system

The delivery system uses liquid N₂O as refrigerant, which is sub-cooled to an appropriate temperature prior to being injected inside the catheter through the injection umbilical tube. The system recovers the N₂O vapour from the catheter and sends it to the hospital scavenging system through a scavenging hose.

Electromechanical valves, pressure transducers and flow meter are used in order to control and monitor the status of different areas of the mechanical assembly.

II.6.2. Pressure Transducers

A pressure transducer is a device that converts input pressure into low-level electrical/electronic signals (volts).

In the CryoConsole, we use three pressure transducers. The first transducer is used to measure the tank pressure. The second transducer is used to measure the pressure delivered by the

proportional valve. That pressure is fed to the PID system that will be used as a feedback to compensate and adjust the proportional valve according to either the temperature or the flow (depending on the catheter used).

The third transducer is used to measure the pressure out of the catheter, thus verifying that N₂O gas is flowing out of the catheter and that no blockage occurs inside the catheter.

II.6.3. Regulators

A pressure regulator is a device that adjusts pressure at a desired value.

Since a pressure of 760 psig is enough to ablate at -75°C, we use two regulators, first to bring down the pressure to 840 psig and second to bring it down to 810 psig.

II.6.4. Solenoid Valves

Solenoid valves are electro-mechanical devices that use a solenoid to control valve activation.

In the CryoConsole, there are five solenoid valves performing specific duties.

- The first valve is the injection solenoid valve turning on and off the injection circuit.
- The second valve is the switch

II.7 Electrical System

II.7.1. Electrical System Overview

The LCD touch screen and the front panel implement the user interface with the CryoConsole. The LCD touch screen is a graphical user interface, which displays CryoConsole status, data and accepts user data and control inputs via screen touches. The front panel consists of controls and displays that show CryoConsole status.

The side IDE panel consists of a mouse, keyboard and analog connectors. The mouse and keyboard connectors are connected to the CPU board through extension cables. **Those connectors should only be used by Field Service representatives.** Also found on this panel is an hour meter that indicates the number of hours the CryoConsole has been powered on. This information is useful for maintenance purposes.

The 1.44 Mb floppy disk drive is mounted in the procedure panel and is used to download patient data on disks and to upload upgrades to the CDM software and catheter identification files.

II.7.2. Power Distribution

The power entry module with voltage selector, thermistors, slow blow fuses, line filter and power switch are rated at 250V operating voltage. The power supply, isolation transformer and line filter are rated at 50/60 Hz.

The voltage selector on the primary side of the isolation transformer is used to enable the 120v/240v conversion.

II.7.2.1. Thermistors

The thermistors are only installed on the power inlet cables of CryoConsole powered by 220V. The thermistors purpose is to protect against any existing inrush current when the system is first switched on.

Section III Operation and Clinical Sequence

Please refer to the *Operator's Manual*, its appendices, as well as the appropriate *Instructions For Use* for the respective catheter.

Section IV Troubleshooting and Maintenance

IV.1 Purpose

This section proposes troubleshooting steps to follow when the CryoConsole is not operating correctly.

IV.2 Scope

This section is separated in two main sections. These sections are the maintenance and the software interface.

IV.3 Definitions and Acronyms

The following definitions and acronyms are used in this section

CDM	CryoAblation Data Manager
CPU	Central Processing Unit
DAQ	Data acquisition board
FPGA	Field Programmable Gate Array
HDD	Hard Disk Drive
NIBBLE	Four binary digits or half of a byte. A nibble can be conveniently represented by one hexadecimal digit.

IV.4 Maintenance

In addition to act as an interface for the user, the CryoAblation Data Manager software installed on the CryoConsole is an interface for the Field Service Representative during a maintenance job.

The representative can access the maintenance section by touching the *Service System* button located on the main panel, shown in **Figure 7**.

Some panels require the use of a keyboard attached to the maintenance panel above the N₂O cylinder. The connector type of the keyboard must be a type AT.

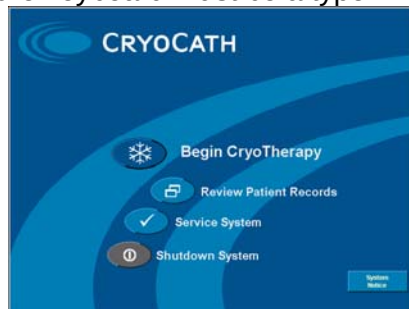


Figure 7 - Main panel

IV.4.1. System Setup panel

This screen is used to monitor the tank level read by the load cell as well as the tank pressure read by the pressure transducer. The user can return to the *Main Panel* by pressing the *Return to Main Panel* button or access the *System Maintenance* panel by pressing the *Advanced Troubleshooting* button. **Figure 8** shows the *System Setup* panel.

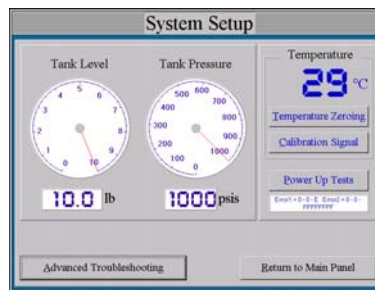


Figure 8 - System Setup panel

IV.4.2. Password panel

When pressing the *Advanced Troubleshooting* button, the system notice #12303 - *The CryoAblation console maintenance should be done by a qualified person* appears. The CryoConsole requires a password to proceed. The low level access password is “user”. Only trained service engineers will have access to all required passwords. The user enters the password and presses *Ok*.



Figure 9 - Password panel

IV.4.3. System Maintenance panel

In this panel, the user can choose between six different sections:

- Password Setup
- Date & Time Setup
- Touch Screen Setup
- Site Setup
- Back Up Patient Files

Figure 10 shows the *System Maintenance* panel.

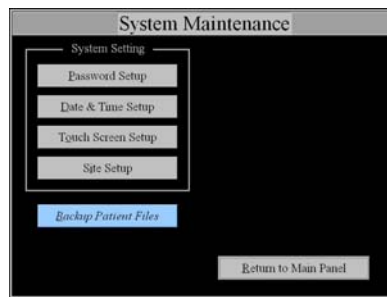


Figure 10 - System Maintenance panel

IV.4.4. Password Setup panel

The purpose of this panel is to change the default password used to access the *System Maintenance* panel. **Figure 11** shows the *Password Setup* panel. Do NOT change the password.



Figure 11 - Password Setup panel

IV.4.5. Date & Time Setup panel

The *Date & Time Setup* panel allows the user to change the date and time of the CryoConsole. **Figure 12** shows the *Date & Time Setup* panel.

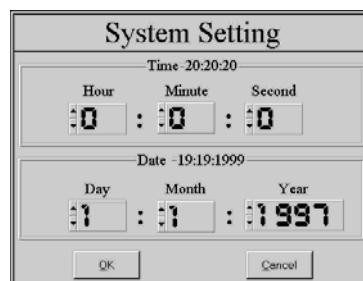


Figure 12 - Date & Time Setup panel

IV.4.6. Touch Screen Setup panel

The purpose of this panel is to calibrate the touch screen when the precision is out of range. When the user pushes on the *Touch Screen Setup* button, the system gives instructions on how to calibrate the touch screen.

IV.4.7. Site Setup panel

The purpose of this panel is to:

- Choose the language of the CryoAblation Data Manager
- Enter the site name
- Update the physician, outcome and diagnosis list of the CryoAblation Data Manager

To set the language, select a language from the *Language* drop-down list.

To enter the site name, write the site name in the *New Site* text box and press the *Update Site* button. This name will appear on the home screen after power-up.

To update one of the three lists, press the desired button (*Physician*, *Outcome*, *Diagnosis*), enter the physician name, outcome or diagnosis in the text box, and press the *Add* button. To delete an entry, select the entry in the list and press *Delete*. Refer to **Figure 13**.

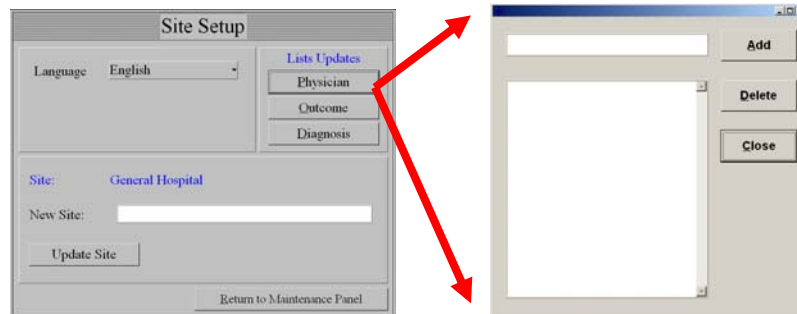


Figure 13 - Site Setup panel

IV.4.8. Back Up Patient File

The purpose of this panel is to make a back up of all the patient data currently stored on the hard drive. When downloaded from this panel, the files are saved in binary format. These files should be downloaded and sent to MDT on a regular basis.

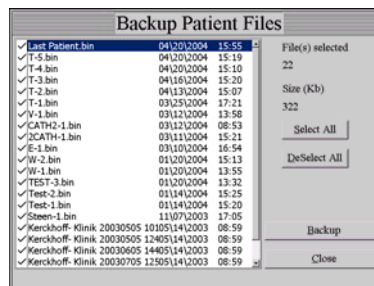


Figure 14 - Backup Patient Files panel

These files help us understand any problem encountered during an injection, see behaviors that may have not appeared during an injection, and helps us identify any possible behavioural patterns.

To download these files:

- 1) Navigate to the **System Maintenance** panel
- 2) Select **Backup Patient Files**
- 3) Insert a floppy disk in the floppy drive
- 4) Press **Backup**. The console will start downloading the patient files that have a check mark to the floppy disk. As the files get saved on the floppy, the checkmark is removed. The console may request you to change the disk if it gets full. The downloading process is finished when all the checkmarks disappear and the green light on the floppy drive turns off.



Figure 15 - Floppy Drive

IV.5 Software Interface

IV.5.1. General information

The CryoConsole includes software called CryoAblation Data Manager (CDM). The main role of the CDM is to acquire and display system data from the hardware, set procedure parameters, save procedure data on the system hard disk and offer some automatic operational features. At system start-up, the software initiates a system self test which ensures proper functionality of the watchdog system and other system and safety features.

Should the self-test fail, the CDM disables the system in order to prevent the user from proceeding and displays a coded error message on the screen.

IV.5.2. Power up test

At start-up, CDM performs a series of tests to verify the CryoConsole hardware and proper operation. If a test fails, two error codes are generated and displayed on the CryoConsole screen.

The first series of power up tests is related to the software integrity, including the testing of the system and configuration files. These files contain important information that could affect the functionality of the system.

The second series of tests is related to the interface between the software and the hardware. These tests verify the proper operation of the data acquisition, digital and analog input/output lines. The data acquisition test is crucial to the performance of other tests; if this test fails, the remaining tests are not performed.

The third series of tests is related to the functionality of the FPGA and the functionality of major safety features. The FPGA component is part of the Watchdog board.

IV.5.3. CDM Codes and Messages

The CDM software uses codes and messages to inform the user the status of the CryoConsole. Always note the message number before calling Technical Support in order to resolve the issue faster.

IV.5.3.1.1. System notice hierarchy

A message to the user is called a system notice. That system notice can be of four different types, depending on the message content. Starting from the least important and going to the most important messages are the notice, caution, the warning and the danger. They respectively are blue, yellow, orange and red. Depending on the source of the notice, the software will assign a different importance to this notice.

To prevent the user from missing a system notice, the first screen appearing to the user is the Message List notice showing all of the system notices. **Figure 16** shows the Message List screen

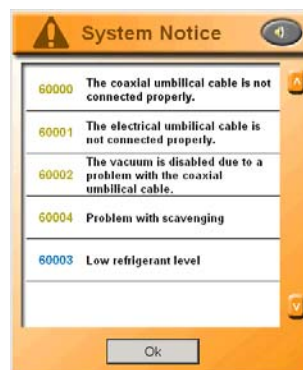


Figure 16 - Message List

The system notices includes a different presentation of the information. It presents the notice with three distinctive fields: Problem, Consequence and Action. **Figure 17** and **Figure 18** show the four notice types.

A blue notice is for information only and no action is required in order to get into the Therapy panel and start and injection.

A yellow notice requires an action in order to go into the Therapy panel.

An orange notice is a failure that will stop an injection or prevent the user from starting one. This notice can be reset and no immediate action needs to be taken.

A red notice is a critical console failure that will cause the termination of the procedure. The console needs to be shutdown and Medtronic CryoCath LP Technical Support must be informed.

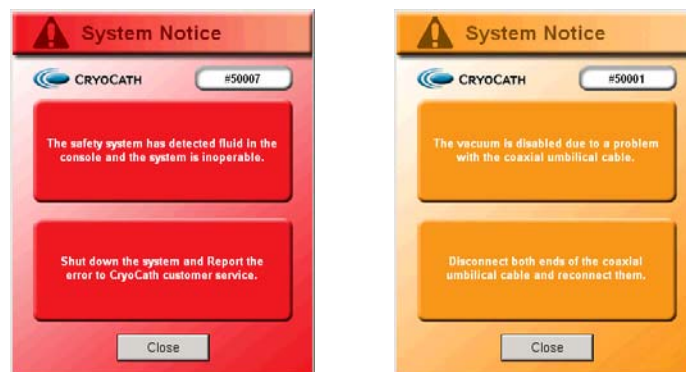


Figure 17 - Danger and Warning System Notice

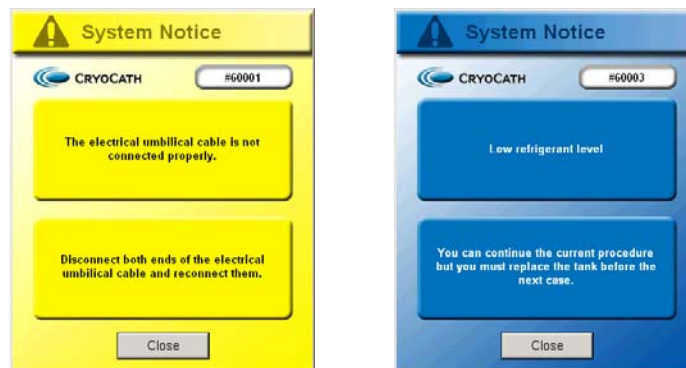


Figure 18 - Caution and Notice System Notice

The notices are part of a numbered series. **Table 3** shows the numbered series in relation with the source of the notice.

Series	Source of the notice
10000	Language confirmation panel
11000	System Start-up Failure
12000-13000-14000	System Warning
15000	File Reading Error
16000	Disk Space
17000	File Writing Error
18000	System Alert
19000	System Error
20000	Directory Error
21000	System Self Test Failure
22000-23000-24000-25000	Message Panel
50000	Hardware Failure
60000	Hardware Warning

Table 3 - Notice series

IV.5.3.1.2. Hardware System Notice

The hardware system notices are the most common errors that are seen in the field while troubleshooting a problem. The watchdog board is the hardware responsible for triggering a hardware failure or a hardware warning. The associated system notices are the 50000 and 60000 series notices.

Whenever the console fails the Power up test, it will give you yellow system notice, #11200, saying “There is a problem with the system Error1: X-X-X Error2: Y-Y-Y). Be sure to note these two error numbers before calling Technical Support.

Table 5 in **Appendix A– System Notices** shows all of the system notices, the problem, the consequence and recommended action. **Table 6** in **Appendix B– Additional Warning Messages** shows warning messages not included in the system notices.

Appendix A– System Notices

Notice	Problem	Consequence	Action	Description
10300	The language you selected is not currently available.	The language was not changed.	Select a different language.	Language selected is not currently available
11200	There is a problem with the system (Error1: X, Error2: Y)	You cannot continue the procedure.	Shut down the system and restart it. If the problem persists, call Medtronic CryoCath LP customer service.	Shutdown system and call service technician. Error1 = X Error2 = Y
12200	There is a problem with the system.	You must take action in order to continue the procedure.	Disconnect the electrical umbilical cable from the catheter and then reconnect it. If the problem persists, call Medtronic CryoCath LP customer service.	You are not able to continue the procedure, Flow detection initialization error
12201	There is a problem with the system.	You must take action in order to continue the procedure.	Disconnect the electrical umbilical cable from the catheter and then reconnect it. If the problem persists, call Medtronic CryoCath LP customer service.	Flow Curve Programming Error (Faulty Tank/Temperature programming)
12202	There is a problem with the system file.	You cannot continue the procedure.	Call Medtronic CryoCath LP customer service.	Incompatible System File
12203	There is a problem with the system file.	You cannot continue the procedure.	Call Medtronic CryoCath LP customer service.	Incompatible Failure File
12204	There is a problem with the catheter file.	You cannot use the catheter.	Disconnect the catheter and reconnect it. If the problem persists, call Medtronic CryoCath LP customer service.	Invalid Catheter Data File
12205	There is a problem with the catheter	You must take action in order to continue the procedure.	Disconnect the catheter electrical umbilical cable and reconnect it. If problem persists, replace the catheter.	Catheter Compatibility / Integrity
12206	The catheter may be outside the patient, causing the catheter tip temperature to be too low.	You must take action in order to continue the procedure.	Check the catheter placement.	Unacceptable catheter use / Catheter Compatibility
12300	There is a problem with the language library: (%s)	The language setting has changed back to English.	Try selecting the language again. If the problem persists, call Medtronic CryoCath LP customer service.	Can't load language library, Library Name
12301	There is a problem with the system file.	The system functionality is limited.	Install or create a new system file.	System file error
12302	There are no messages		Click Ok to continue	The Failure Database is empty
12303	The CryoAblation console maintenance should be done by a qualified person.		Click Ok to continue	The CryoAblation console maintenance should be done by a qualified person.
12304	The system could not save the password.	The password was not changed.	Try to change the password again. If the problem persists, call Medtronic CryoCath LP customer service.	Field Password Saving Error
12305	There is a problem with the message file.	You cannot view the messages.	Click Ok to continue.	Failure file not found
12306	The system could not save	The language was not	Select a different	Error Saving Language

Notice	Problem	Consequence	Action	Description
	your language selection.	changed.	language, or install or create a new configuration file.	Code
12307	There is a problem with the configuration file.	The system could not save the temperature calibration parameters.	Try again. If the problem persists, call Medtronic CryoCath LP customer service.	Calibration Saving Error
12308	The system could not open the patient file.	You cannot view the patient file.	Try again. If the problem persists, call Medtronic CryoCath LP customer service.	Patient file not found
12309	The system could not open the patient file.	You cannot view the patient file.	Try again. If the problem persists, call Medtronic CryoCath LP customer service.	Patient file Empty (file check code is incorrect)
12310	The system could not open the patient file.	You cannot view the patient file.	Try again. If the problem persists, call Medtronic CryoCath LP customer service.	Patient Record Reading Error (Pt file cannot be opened)
12311	The system could not open the patient file.	You cannot view the patient file.	Try again. If the problem persists, call Medtronic CryoCath LP customer service.	Invalid Patient File (file check code is incorrect)
12312	The patient file is empty.	You cannot view the patient file.	Call Medtronic CryoCath LP customer service.	Patient Record Empty
12313	There is a problem with the message file.	The system cannot update the file.	Install or create a new messages file.	Failure file error (setcdmver)
12314	There is a problem opening the configuration file.	The system cannot update the file.	Install or create a new configuration file.	Configuration file error (setcdmver)
12315	There is a problem with the catheter file.	The system cannot load the catheter parameters.	Delete this file.	Invalid Catheter Data File, Please delete it
12316	The catheter name field is empty.	You cannot continue without entering a catheter name.	Enter the catheter name.	Please enter Catheter Name
12317	The temperature has not yet reached 20-30 degrees.	You cannot calibrate the temperature yet.	Wait until the board reaches the appropriate temperature.	Temperature calibration can not be performed, Please check patient board temperature
12318	There is an error copying the patient file.	You cannot copy the patient file to diskette.	Try again. If the problem persists, call Medtronic CryoCath LP customer service.	File copying error, General input output error with the following (patient Filename)
12319	There is an error copying flow curve data.	You cannot copy the flow curve data to diskette.	If the problem persists, contact Medtronic CryoCath LP customer service.	File copying error, General input output error with the following (flow curve data Filename)
12320	The patient name field is empty.	You cannot continue without entering a patient name.	Enter the patient's name in order to continue.	Please enter patient name in order to continue
12321	There is no diskette in the drive.		Insert a diskette and press Ok.	No disk in the floppy drive, Please insert a disk
12322	Catheter file copying error: %s	Cannot copy catheter file to the floppy	Try again, and if problem persists call Medtronic CryoCath LP customer service	File copying error. General input output error with the following (Filename)
12323	There is a problem with the catheter file %s.	You cannot use the catheter.	Disconnect the catheter and reconnect it. If the problem persists, call Medtronic CryoCath LP customer service.	Catheter file error. Following file is not a valid catheter file (filename)
13300	The system cannot load the touch screen calibration file.	You cannot calibrate the touch screen.	Try again. If the problem persists, call Medtronic CryoCath LP customer service.	Could not load Calibration Library

Notice	Problem	Consequence	Action	Description
14300	The console ID is empty.	You cannot continue without entering a console ID.	Enter the console ID now.	Console ID is not set yet, Please, do it now
14301	The hard drive is almost full.	You may not be able to complete another procedure.	Free some space on the hard drive before the next procedure.	The hard disk is almost full, Free some space before the next procedure
15300	There is a problem finding the file.	You cannot copy the file to diskette.	Try again. If the problem persists, call Medtronic CryoCath LP customer service.	File not found or directory in path not found (copy fail file, pt db, conv pt db)
15301	There is a problem finding the file.	You cannot copy the file to diskette.	Try again. If the problem persists, call Medtronic CryoCath LP customer service.	File not found, please remove disk (copy cath db)
15302	There is a problem copying the file.	You cannot copy the file to diskette.	Try again. If the problem persists, call Medtronic CryoCath LP customer service.	General I/O error occurred (copy fail file, mkdir, copy conv pt db)
15303	There is a problem copying the file.	You cannot copy the file to diskette.	Try again. If the problem persists, call Medtronic CryoCath LP customer service.	Insufficient memory to complete operation (copy fail file, mkdir, copy conv pt db)
15304	There is a problem finding the file.	You cannot copy the file to diskette.	Try again. If the problem persists, call Medtronic CryoCath LP customer service.	Invalid path (copy fail file)
15305	There is a problem copying the file.	You cannot copy the file to diskette.	Try again. If the problem persists, call Medtronic CryoCath LP customer service.	Access denied (copy fail file & pt db)
16300	There is no diskette in the drive.		Insert a diskette and press Ok.	No disk in the floppy drive, Please insert a disk
16301	There is not enough space on the diskette.		Insert another diskette and press Ok.	Not enough disk space, Change disk
17300	There is a problem copying the file.	You cannot copy the file to diskette.	Try again. If the problem persists, call Medtronic CryoCath LP customer service.	One of the path components not found (Copy pt db & Mkdir)
17301	There is a problem copying the file.	You cannot copy the file to diskette.	Try again. If the problem persists, call Medtronic CryoCath LP customer service.	General I/O error occurred
17302	There is a problem copying the file.	You cannot copy the file to diskette.	Try again. If the problem persists, call Medtronic CryoCath LP customer service.	Insufficient memory to complete operation
17303	There is a problem copying the file.	You cannot copy the file to diskette.	Try again. If the problem persists, call Medtronic CryoCath LP customer service.	Invalid path
17304	There is a problem copying the file.	You cannot copy the file to diskette.	Try again. If the problem persists, call Medtronic CryoCath LP customer service.	Access denied
17305	There is a problem copying the file.	You cannot copy the file to diskette.	Try again. If the problem persists, call Medtronic CryoCath LP customer service.	Specified path is a directory, not a file.
17306	There is not enough space on the diskette.		To continue, insert another diskette and press Ok. Otherwise, press Cancel.	Disk is full (w/ chg disk in Archive & ConvDb)
18300	There is a problem with the	You cannot continue the	Shut down the system and	You are not able to

Notice	Problem	Consequence	Action	Description
	system.	procedure.	restart it. If the problem persists, call Medtronic CryoCath LP customer service.	continue the procedure, Reboot System
19300	There is a problem copying the file.	You cannot copy the file to diskette.	Try again. If the problem persists, call Medtronic CryoCath LP customer service.	Access to floppy disk is denied, check disk (copy fail file and conv db)
19301	There is a problem finding the file.	You cannot copy the file to diskette.	Try again. If the problem persists, call Medtronic CryoCath LP customer service.	File not found or directory in path not found
19302	There is a problem finding the file.	You cannot copy the file to diskette.	Try again. If the problem persists, call Medtronic CryoCath LP customer service.	General I/O error occurred
19303	There is a problem copying the file.	You cannot copy the file to diskette.	Try again. If the problem persists, call Medtronic CryoCath LP customer service.	Insufficient memory to complete operation
19304	There is a problem copying the file.	You cannot copy the file to diskette.	Try again. If the problem persists, call Medtronic CryoCath LP customer service.	Invalid path (for either of the file names).
19305	There is a problem copying the file.	You cannot copy the file to diskette.	Try again. If the problem persists, call Medtronic CryoCath LP customer service.	Specified source path is a directory, not a file (copy fail file)
19306	There is a problem copying the file.	You cannot copy the file to diskette.	Try again. If the problem persists, call Medtronic CryoCath LP customer service.	Disk is full
20300	There is a problem copying the file.	You cannot copy the file to diskette.	Try again. If the problem persists, call Medtronic CryoCath LP customer service.	One of the path components not found
20301	There is a problem copying the file.	You cannot copy the file to diskette.	Try again. If the problem persists, call Medtronic CryoCath LP customer service.	General I/O error occurred
20302	There is a problem copying the file.	You cannot copy the file to diskette.	Try again. If the problem persists, call Medtronic CryoCath LP customer service.	Insufficient memory to complete operation
20303	There is a problem finding the file.	You cannot copy the file to diskette.	Try again. If the problem persists, call Medtronic CryoCath LP customer service.	Invalid path
20304	There is a problem copying the file.	You cannot copy the file to diskette.	Try again. If the problem persists, call Medtronic CryoCath LP customer service.	Access denied
20305	There is a problem copying the file.	You cannot copy the file to diskette.	Try again. If the problem persists, call Medtronic CryoCath LP customer service.	Disk is full
21200	There is a problem with the system.	You cannot continue the procedure.	Shut down the system and restart it. If the problem persists, call Medtronic CryoCath LP customer service.	You are not able to continue the procedure, Call a service technician
22400	System Shut Down	Please wait while your		Please wait while your

Notice	Problem	Consequence	Action	Description
		system shuts down		system shuts down
22401	Target Temperature Not Attained	Minimum temperature is warmer than %d °C		Minimum temperature is warmer than X °C
22402	System Shut Down	Please close gas tank		Please close gas tank
22403	System Startup	Make sure the refrigerant tank has been opened.		Make sure the refrigerant tank is opened 2 turns counter clockwise
22500		Catheter integrity test, injection will be enabled shortly.		Injection will be enabled in X seconds
22501		System self test - Please wait ...		System Startup - Self test delay
22502		Refilling Reservoir, injection will be enabled shortly.		

23300	Are you sure you want to exit?	If you exit, the system will close this patient file. As a result, you would not be able to continue this patient's procedure and would have to create a new patient file.	To exit, press Yes. Otherwise, press No.	Are you sure you want to exit from this panel ?
23301	The patient file will not fit on one diskette.	You will need multiple diskettes.	To continue, press Ok. Otherwise, press Cancel.	Not enough disk space, You will need multiple disks, do you wish to continue? (Conv db copy to disk)
23302	Are you sure you want to end the procedure?	If you end procedure, the system returns to the main screen and closes the patient file.	To end the procedure, press yes. Otherwise, press No.	End Procedure, By ending the procedure you will return to the main screen and close the patient file. Are you sure you want to end the procedure? (Response to user selecting abort in failure panel)
23400	File Delete	Are you sure you want to delete the file?		File Delete, Are you sure you want to delete the file? (pt db)
23401	System Shut Down	Are you sure you want to quit?		System Shutdown, Are you sure you want to quit?
23402	Patient Database	This patient file already exists. Do you want to overwrite it?		Database Conversion, Database already exists, overwrite?
23403	Temperature Calibration	Are you sure you want to save the temperature calibration?		System Saving, Are you sure you want to save these data?
23404	Catheter File Database	This catheter file already exists. Do you want to overwrite it?		Warning, Do you want to overwrite the existing file (Overwriting catheter file)
23405	Analog Data	Overwrite the existing analog data file?		Overwrite analog data file

24300	There is not enough space on the diskette.		To continue, insert another diskette and press Ok. Otherwise, press Cancel.	Change disk then press Ok//Conv or archive, ok to continue else cancel
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25400	Error in File Selection	Click Ok to retry, otherwise click Cancel and copy 'c:\cryosys\system\AnalogData.txt' manually		Error in File Selection, Click OK to Retry or Cancel and copy c:\cryosys\system\AnalogData.txt manually
25401	Copy Failed	Click Ok to retry, otherwise click Cancel and copy 'c:\cryosys\system\AnalogData.txt' manually		Copy Failed, Click OK to Retry or Cancel and copy c:\cryosys\system\AnalogData.txt manually

Notice	Problem	Consequence	Action	Description
		gData.txt manually		ata.txt manually
50000	The electrical umbilical cable is not connected properly.	Injection has stopped. You must take action in order to continue the procedure.	Disconnect both ends of the electrical umbilical cable and reconnect them.	816 Catheter electrical connection failure
50001	The vacuum is disabled due to a problem with the coaxial umbilical cable.	Injection has stopped. You must take action in order to continue the procedure.	Disconnect both ends of the coaxial umbilical cable and reconnect them.	817 Vacuum connection failure
50002	The coaxial umbilical cable is not connected properly.	You must take action in order to continue the procedure.	Disconnect both ends of the coaxial umbilical cable and reconnect them.	Baseline Flow
50003	The pressure is low in the system.	Injection has stopped. You must take action in order to continue the procedure.	Ensure refrigerant tank is open.	819.1 Low gas pressure X psi, ensure refrigerant tank is open
50005	Catheter leak is detected.	Injection has stopped. You must take action in order to continue the procedure.	Replace the catheter	821 Catheter leak is detected
50006	Blood is detected inside the catheter handle	Injection has stopped. You must take action in order to continue the procedure.	Replace the catheter	822 Blood is detected inside the catheter handle
50007	There is fluid in the console.	You cannot continue the procedure.	The system is inoperable. Please shut it down and call Medtronic CryoCath LP customer service.	823 Fluid is detected inside console vacuum line
50008	There is a problem with the system.	Injection has stopped.	Try again. If the problem persists, shut down the system and restart it. If there is still a problem, call Medtronic CryoCath LP customer service.	824 Software Failure
50009	There is a problem with the system.	Injection has stopped.	Try again. If the problem persists, shut down the system and restart it. If there is still a problem, call Medtronic CryoCath LP customer service.	825 Failure has been initiated by the CPU.
50010	There is a problem with the system and the temperature could drop below acceptable limits.	You must take action in order to continue the procedure.	Disconnect the catheter electrical umbilical cable and reconnect it. If problem persists, call Medtronic CryoCath LP customer service.	826 Temperature Threshold programming
50011	The path of the refrigerant is obstructed.	Injection has stopped. You must take action in order to continue the procedure.	Disconnect the coaxial umbilical cable from the console, make sure that the port it was attached to is clear of obstruction, and reconnect the coaxial umbilical cable to the console.	819.2 Ensure the inside of console coaxial port is clear
50012	The path of the refrigerant is obstructed.	Injection has stopped. You must take action in order to continue the procedure.	If problem persists, replace the coaxial umbilical cable. If there is still a problem, replace the catheter.	819.3 Ensure integrity of refrigerant path in catheter/umbilical
50013	The refrigerant level is too low to continue.	You cannot continue the procedure.	Replace the refrigerant tank.	829 Refrigerant level failure
50014	There is a problem with the console.	You must take action in order to continue the procedure.	Try again. If the problem persists, shut down the system and restart it. If there is still a problem, call Medtronic CryoCath LP customer service.	830 Sub cooler compressor failure
50016	The CryoMapping temperature exceeded the PRESET range of	Injection has stopped. You must take action in order to continue the procedure.	Position the catheter tip so that it makes better contact with the tissue.	832 Improve catheter tip-tissue contact

Notice	Problem	Consequence	Action	Description
	temperature.			
50017	The console is running hot.	Injection has stopped. You cannot continue the procedure.	Check whether the fans are working. Shut down the system and wait 10 minutes before restarting it. If the problem persists, call Medtronic CryoCath LP customer service.	833 Console temperature is high
50018	The refrigerant is not cold enough.	Injection has stopped. You cannot continue the procedure.	Wait 10 minutes before continuing the procedure. If the problem persists, call Medtronic CryoCath LP customer service.	834 Refrigerant temperature is high
50021	Problem with scavenging	Injection stopped. You must take action in order to continue the procedure.	Ensure that the hospital scavenging system is turned on and that the scavenging hose is securely attached.	837 Scavenging system failure
50022	There is a problem with the console	You must take action in order to continue the procedure	Try again. If the problem persists, shut down the system and restart it. If there is still a problem, call Medtronic CryoCath LP customer service.	838 Vacuum pump failure
50024	There is a problem with the refrigerant vent.	You must take action in order to continue the procedure.	Disconnect the coaxial umbilical cable from the console and make sure that the port it was attached to is clear of obstruction. Make sure there is no obstruction in the catheter or coaxial umbilical cable, and reconnect it.	840 Vent system failure
50025	There is a problem with the injection process.	Injection will not start. You must take action in order to continue the procedure.	Try again. If the problem persists, call Medtronic CryoCath LP customer service.	841 User Request backup interface failure.
50026	There is a problem with the injection process.	Injection has stopped. You must take action in order to continue the procedure.	Try again. If the problem persists, call Medtronic CryoCath LP customer service.	842 Injection valve (S1) failure.
50027	There is a problem with the injection process.	Injection has stopped. You must take action in order to continue the procedure.	Try again. If the problem persists, call Medtronic CryoCath LP customer service.	843 Vent valve (S2) failure.
50028	There is a problem with the injection process.	Injection has stopped. You must take action in order to continue the procedure.	Try again. If the problem persists, call Medtronic CryoCath LP customer service.	844 Vacuum valve (S3) failure.
50029	There is too much refrigerant flowing.	Injection has stopped. You must take action in order to continue the procedure.	Replace the coaxial umbilical cable.	820.1 Change coaxial umbilical
50030	There is too much refrigerant flowing.	Injection has stopped. You must take action in order to continue the procedure.	Position the catheter tip so that it makes better contact with the tissue.	820.2 Improve catheter tip-tissue contact
50031	There is a problem with the injection process.	Injection has stopped. You must take action in order to continue the procedure.	Try again. If the problem persists, call Medtronic CryoCath LP customer service.	847 Vent valve (S6) failure.
60000	The coaxial umbilical cable is not connected properly.	You must take action in order to continue the procedure.	Disconnect both ends of the coaxial umbilical cable and reconnect them.	848 Baseline Flow
60001	The electrical umbilical cable is not connected	You must take action in order to continue the	Disconnect both ends of the electrical umbilical	849 Check electrical connector

Notice	Problem	Consequence	Action	Description
	properly.	procedure.	cable and reconnect them.	
60002	The vacuum is disabled due to a problem with the coaxial umbilical cable.	You must take action in order to continue the procedure.	Disconnect both ends of the coaxial umbilical cable and reconnect them.	850 Check vacuum connector
60003	Low refrigerant level	You may run out of refrigerant	Replace refrigerant tank	851 Check refrigerant tank level
60004	Problem with scavenging	You must take action in order to continue the procedure.	Ensure that the hospital scavenging system is turned on and that the scavenging hose is securely attached.	852 Check scavenging system

Table 5- System Notices

Appendix B– Additional Warning Messages

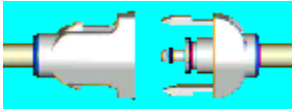
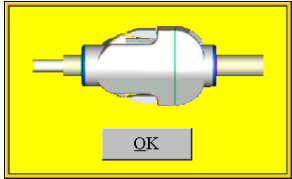
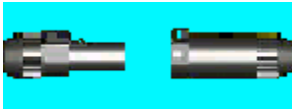
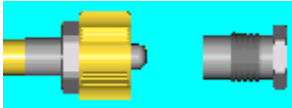
WARNING Messages	Possible Corrective Action
Check refrigerant tank level Check Refrigerant Tank Level.	• Verify the cylinder level and cylinder pressure in the system set-up panel. • Center the cylinder on the plate support (Load Cell). • Verify the hose connection has no bends or kinks. • Verify the actual cylinder weight, using a hospital's calibrated scale. • Replace the cylinder after completion of the procedure.
Check mechanical connectors 	• Verify the coaxial connections • Replace the coaxial umbilical • Replace the catheter Note: This animation can occur in the patient screen when the baseline flow is around the threshold value of 100 sccm. This usually means there is a leak in the system or the flow meter needs to be calibrated.
Vacuum Connection Panel 	Upon pressing “OK” field and the warning persists: • Verify coaxial connections, then “OK”. If the warning persists, • Replace the coaxial umbilical, then “OK”. If the warning persists, • Replace the catheter
Electrical Connector Animation 	• Verify the electrical connections • Replace the ECG box • Replace the Electrical Umbilical • Replace the catheter
Scavenging Connector Animation 	• Verify the scavenging connection at the CryoConsole and wall outlet. • Verify the hospital's scavenging system is working (in case of an active system).

Table 6- Warning messages corrective action

Appendix C– Guideline & Specifications for N₂O refilling

- The refrigerant to be refilled is N₂O (UN 1070) 99.5% liquid phase with a humidity level less than 50ppm. It is important that the refiller supply the user with a “Certificate of Analysis” (at each refilling), which would provide proof that the refilled refrigerant met or exceeded the specifications indicated above. It is also important that the ‘Certificate of Analysis’ refers to the gas quality **after** it has been put into the refrigerant tank.
- The refrigerant must be refilled in the supplied Medtronic CryoCath LP N₂O tank. The approximate amount of refrigerant to refill is 10lbs for North America and 8.3lbs for Europe. These tanks consist of three (3) parts: cylinder, dip-tube and valve. It is important that the gas supplier be aware of the stainless steel dip-tube. The gas supplier must connect to the N₂O tank valve outlet connector “CEODEUX C10500275”.
- Provided that the gas refiller has the proper equipment and adaptors to attach to the Medtronic CryoCath LP N₂O tank and that they provide an appropriate Certificate of Analysis on the refrigerant quality specifications, then it is acceptable for Medtronic customers to obtain their N₂O tank refilled by a supplier of their choice.
- All parties handling the refrigerant tanks **must** be aware that when the N₂O tanks have any refrigerant in them at all they are considered to be containing dangerous goods (I.A.T.A Class 2.2 Non Flammable, Non-toxic Gas and Class 5.1 Gases Oxidizer) and should be handled accordingly.